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A

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
ML-0362C2

Total Pages in this Submission
3

JC835 U.S. PTO 05/26/00

JC759 U.S. PTO 09/579599 05/26/00

TO THE ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

CONFOCAL IMAGING THROUGH THICK DERMAL TISSUE

and invented by:

James M. Zavislan and Jay M. Eastman

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: **09/001,016**

Which is a:

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: **08/650,684**

Which claims priority to Provisional Application No. 60/001,141, filed 07/13/95.

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having **12** pages and including the following:
   - a. ☒ Descriptive Title of the Invention
   - b. ☐ Cross References to Related Applications *(if applicable)*
   - c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   - d. ☐ Reference to Microfiche Appendix *(if applicable)*
   - e. ☒ Background of the Invention
   - f. ☒ Brief Summary of the Invention
   - g. ☒ Brief Description of the Drawings *(if drawings filed)*
   - h. ☒ Detailed Description
   - i. ☒ Claim(s) as Classified Below
   - j. ☒ Abstract of the Disclosure

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Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*

   a. ☒ Formal b. ☐ Informal Number of Sheets 2

4. ☒ Oath or Declaration

   a. ☐ Newly executed *(original or copy)* ☐ Unexecuted

   b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

   c. ☒ With Power of Attorney ☐ Without Power of Attorney

   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☒ Incorporation By Reference *(usable if Box 4b is checked)*
   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*

   a. ☐ Paper Copy

   b. ☐ Computer Readable Copy

   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☒ Assignment Papers *(cover sheet & documents)* (copy from prior application)

9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☒ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☒ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

    ☐ First Class ☒ Express Mail *(Specify Label No.):* EL641552251US

UTILITY PATENT APPLICATION TRANSMITTAL
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Docket No.
ML-0362C2

Total Pages in this Submission
3

Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: **1**

17. ☒ Additional Enclosures *(please identify below):*

CHANGE OF ADDRESS OF ATTORNEY

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	17	- 20 =	0	x $9.00	$0.00
Indep. Claims	3	- 3 =	0	x $39.00	$0.00
Multiple Dependent Claims (check if applicable) ☐					$0.00
				BASIC FEE	$345.00
OTHER FEE *(specify purpose)*					$0.00
				TOTAL FILING FEE	$345.00

☒ A check in the amount of **$345.00** to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **50-1101** as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **May 26, 2000**

Kenneth J. LuKacher

Signature

Kenneth J. LuKacher
Attorney for Applicants
Registration No. 38,539
South Winton Court
3136 Winton Road South, Suite 304
Rochester, New York 14623
Telephone: (716) 424-2670

KJL/tsm
cc:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN	Docket No. ML-0362C

Serial No.	Filing Date	Patent No.	Issue Date
N/A	Concurrently herewith	N/A	N/A

Applicant/ Patentee: **Zavislan, James M. and Eastman, Jay M.**

Invention: **CONFOCAL IMAGING THROUGH THICK DERMAL TISSUE**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
- ☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: **Lucid Technologies, Inc.**

ADDRESS OF CONCERN: **235 Middle Rd, Henrietta, NY 14467**

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☒ the specification filed herewith with title as listed above.
- ☐ the application identified above.
- ☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: **James M. Zavislan**

TITLE OF PERSON SIGNING OTHER THAN OWNER: **Vice President**

ADDRESS OF PERSON SIGNING: **5 Wandering Trail**
Pittsford, New York

SIGNATURE: James M Zavislan DATE: 16 December 1997

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Zavislan et al.
Application No:	Continuation of USSN 09/001,016, filed Dec. 30, 1997, which is a Continuation of USSN 08/650,684, filed May 20, 1996, with priority to Provisional Application No. 60/001,141, filed July 13, 1995
Filed:	Concurrently herewith
Title:	CONFOCAL IMAGING THROUGH THICK DERMAL TISSUE
Examiner:	Yarnell, B. Art Unit: 3739
Attorney Docket:	ML-0362C2

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend the above-identified application as follows:

In the Title:

Please replace the title with "Microscopic Imaging Apparatus and Method".

In the Abstract:

Please replace the abstract with the following:

-- An imaging apparatus is provided for imaging tissue samples substantially beneath the surface of the tissue sample. The apparatus includes an objective lens and a window defining a tissue contacting surface in pressure contacting relationship with the surface of the tissue sample when the tissue sample is imaged by the objective lens to view tissue structures for pathological applications. The objective lens focuses an illumination beam through the window to the tissue sample and receives returned reflected light of the beam representative of one or more sections of the tissue sample. The apparatus enables a method for in vivo observation of tissue for diagnosis of conditions substantially beneath the surface of the tissue sample. Both two and three-dimensional imaging may be provided for diagnosis and location of basal cell carcinomas and melanomas, and so as to enable visualization of tumor borders prior to excision. --

In the Specification:

Page 1, line 3, after "application" insert -- is a continuation of application Serial No. 09/001,016 filed December 30, 1997, now pending, which is a continuation of application Serial No. 08/650,684 filed May 20, 1996, now U.S. Patent No. 5,788,639, which --.

Page 1, line 3, delete "co-" and line 4, delete "pending".

Page 6, line 5, after "display." insert -- The tissue section images visualized on the display 46 can provide diagnosis in the location of tumors or other conditions beneath the surface of dermatological tissue, such as basil cell carcinomas and melanomas, and thus, if needed, visualization of the borders of the tumor prior to excision of tissue. --

In the Claims:

Please add new Claims 27-43:

27. A microscopic imaging apparatus for imaging tissue samples for pathological applications through an objective lens, said apparatus comprising:

an objective lens; and

a window having a surface capable of being in a pressure contact relationship with the surface of said tissue sample in which said window is in optical communication with said objective lens.

28. The apparatus according to Claim 27 further comprising an illumination beam which is focused by said objective lens through said window to said tissue sample.

29. The apparatus according to Claim 28 wherein said objective lens receives returned light from said tissue sample representing a tissue section.

30. The apparatus according to Claim 28 further comprising a light source for said illumination beam.

31. The apparatus according to Claim 28 wherein said window is transparent to said illumination beam.

32. The apparatus according to Claim 27 further comprising a housing capable of being handheld having at least said objective lens and said window.

33. The apparatus according to Claim 27 wherein said objective lens has a numerical aperture of less than one.

34. A system for imaging and diagnosing a tissue sample for pathological applications comprising:

an objective lens;

a window having a surface capable of being in a pressure contact relationship with the surface of said tissue sample;

an illumination beam which is focused by said objective lens through said window to said tissue sample, in which said objective lens receives returned light from said tissue sample representing a tissue section; and

means for displaying said tissue section to diagnose abnormalities in said tissue sample.

35. The system according to Claim 34 wherein said abnormalities represent a tumor.

36. The system according to Claim 34 wherein said tumor represents one of carcinomas and melanomas.

37. A method for diagnosing a tumor in images of one or more sections of tissue comprising the steps of:

placing said tissue against a window having a surface in a pressure contact relationship with the surface of said tissue;

imaging the tissue through an objective lens to provide at least one image of a section of the tissue; and

diagnosing in said image one or more cells of a tumor in said tissue.

38. The method according to Claim 37 further comprising the step of focusing an illumination beam with said objective lens through said window to said tissue sample.

39. The method according to Claim 38 further comprising the step of providing a light source for said illumination beam.

40. The method according to Claim 37 further comprising the step of visualizing the borders of the tumor in said image.

41. The method according to Claim 40 further comprising the step of excising the tumor cells from said tissue.

42. The method according to Claim 40 wherein said imaging step further comprises the steps of:

receiving return light from said tissue representing a tissue section; and

converting the returned light into electrical signals; and

processing said electrical signals to provide a display of said image of said tissue section.

43. The method according to Claim 37 wherein said tumor represents one of carcinomas and melanomas.

Please Cancel Claims 1-26.

Remarks

The title and abstract have been amended to better correspond to the claims of the application.

The specification has been amended on page 6. This amendment is not new matter as diagnosis of tissue is supported on page 3, line 9, and the abstract of the application supports observation of tissue for diagnosis of conditions beneath the surface of tissue, such as skin, diagnosis and location of tumors, such as carcinomas and melanomas, and visualization of tumor borders prior to excision. The display is described on page 6, lines 4-5, and shown in FIG. 2. The subject matter of the abstract is not new matter, as it is considered part of the specification, and may support claims. See In re Armbruster, 185 USPQ 152, 154 (CCPA 1975), and MPEP §608.01(b). Entry of the amendment is thus requested.

Claims 1-26 are cancelled, and Claims 27-43 have been added for consideration by the Examiner.

Respectfully submitted,

Dated: May 26, 2000

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Confocal Imaging Through Thick Dermal Tissue

Abstract

A handheld confocal imaging system for in vivo observation of dermal and subdermal tissue allows diagnosis of conditions substantially beneath the surface of the skin. A confocal head has optics which scan the tissue so as to provide images of vertical sections of the tissue. Both two and three dimensional imaging may be provided for diagnosis and location of basal cell carcinomas and melanomas, and so as to enable visualization of tumor borders prior to excision.

Confocal Imaging Through Thick Dermal Tissue

This application claims the priority benefit of co-pending provisional application, Serial No. 60/001,141, filed July 13, 1995.

Field Of The Invention

The present invention relates to handheld confocal imaging system for in vivo clinical examinations of dermal and subdermal tissues using non-ionizing radiation, and particularly laser radiation which is of a wavelength capable of penetrating into the skin.

The invention is especially suitable for providing an instrument for dermal pathology applications. The invention is also applicable for visualizing sections in other scattering media than tissue. The invention enables the use of a laser as a source of illumination. The instrument may provide data to image processing computers, which may be programmed to provide high resolution images of dermal sections.

Background Of The Invention

Systems have been proposed for viewing the surface areas of the skin or the external surfaces of internal tissue. Viewing without scanning is described in Pennypacker, U.S. Patent 4,817,622, issued April 4, 1989. Examination of internal tissue surfaces by means of beam scanning are proposed in Harris, U.S. Patent 5,120,953, issued June 9, 1992, Ohki, U.S. Patent 5,122,653 issued June 16, 1992, Webb, U.S. Patent 4,768,874 issued September 6, 1988 and Pflibsen, U.S. Patent 4,991,953 issued February 12, 1991. Such proposals have not provided a handheld instrument which is readily usable by a surgeon in clinical examinations for imaging the epidermis and dermis, especially in vertical sections or in horizontal sections at desired depths below the surface of the skin.

Summary Of The Invention

Accordingly, it is the principal object of the present invention to provide and improve clinical dermatological imaging system.

It is another object of the invention to provide an improved confocal imaging system which provides images of dermatological tissues and avoids the need for biopsies to detect the location of such abnormalities as basal cell carcinomas and melanomas.

It is a still further object of the present invention to provide an improved confocal dermatological imaging system which does not require ionizing radiation and may use a laser beam.

It is a still further object of the present invention to provide an improved confocal imaging system which provides in vivo imaging of dermatological tissue both at and below the skin and which may be handheld and which is capable of operating in various scattering media.

It is a still further object of the present invention to provide an improved confocal dermatological imaging system which may use a computer to generate images from data produced by the optics which provides confocal imaging and to display or provide images for further evaluation or computer enhancement.

Brief Description Of The Drawings

The foregoing objects, features and advantages of the invention will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

FIG. 1 is schematic diagram of a confocal imaging system embodying the invention;

FIG. 1a is a plan view of the head of the system shown in FIG. 1;

FIG. 2 is a block diagram of the system shown in FIG. 1, and especially the computer control and imaging system for acquisition and processing of the optical image;

FIG. 3 is a schematic diagram of the handheld confocal imaging system of FIG. 2 in use.

Detailed Description Of The Invention

Referring to FIG. 1 there is shown a system 10 for in vivo diagnosis of dermatological tissues. The system 10 may be embodied in a handheld head 32 as shown in FIG. 1a and schematically in FIG. 3.

Referring more particularly to FIG. 1 there is shown a system 10 (or instrument) which contains optics of the type which are used in optical data storage heads which are used in recording and reading optical disks. Light from a laser diode, contained in a laser and collimator assembly 12, is collimated by a diffraction limited lens in the assembly 12 and is incident at an oblique angle on a beam splitter assembly 14. Refraction at this oblique angle causes the elliptical laser diode beam to become circular in cross-section. The circular beam passes through the beam splitter assembly 14 and a quarter wave plate 16 and is focused into the tissue 22 via a contact window 20 (a glass window plate) spaced from the sample, specimen or tissue 22 being examined, preferably by an optical contact liquid 21. In the event the sample is viscus or liquid, it may be located in a sample well (not shown).

The circular beam which passes through the beam splitter assembly 14 and the quarter wave plate 16 is focused into the sample by a precision focusing lens 18, which suitably has a numerical aperture of 0.5 and a focal length of 4.3 millimeters. These dimensions and parameters are exemplary and demonstrate that the optical system 10 may be miniaturized so as to be adapted to be handheld.

The quarter wave plate 16 converts the incident linear polarization from the laser in assembly 12 to circular

polarization, i.e., the quarter wave plate is oriented 45° to the incident polarization. In other words, the beam from plate 16 is circularly polarized. The focusing lens 18 is movable both in a direction along its optical axis and laterally as indicated by the arrows 24 and 25, respectively. Position mechanical actuators 34 (FIG. 1a) may be used for moving the lens 18, and thereby control position of the focus spot of beam in the sample. These actuators 34 may be similar to those used in optical disk systems. The lens 18 may be mounted on a pair of such mechanical actuators. The actuators 34 provide lateral and vertical scanning of the focused laser beam in the tissue sample.

The focusing lens 18 also collects scattered light reflected from the sample. The amount of coherent light scattered back into the detection system (which includes lens 18, plate 16 and assembly 14) depends upon local variations of the refractive index and the absorption in the immediate neighborhood of the focus spot. This coherent light may be defined as the component of the reflected light having a circular polarization orthogonal to the polarization of the beam focused into the tissue sample. The scattered light is incident to plate 16 and then to beam splitter assembly 14. The plate 18 converts the coherent component of the scattered light into linear polarization, where beam splitter assembly 14 directs by reflection (or filters) the coherent light component of the scattered light at the beam splitting surface 15 in the beam splitter assembly 14. The reflected light passes through a relay lens 26. The light from relay lens 26 may be reflected from a pair of fold mirrors 28 (See also FIG. 1a). These fold mirrors 28 may be part of the beam splitter assembly 14. The relay lens 26 may also be part of this assembly 14.

The scanned light from the focus spot is reflected from the fold mirrors 28 to a pinhole photodetector assembly 30, which may also be considered part of the detection system. The fold mirrors 28 are used to make the instrument more compact. A prism assembly may alternatively be used, which is part of the beam

splitting assembly 14, and allows the samples to be placed face down. This orientation allows gravity to assist in maintaining the sample in a stable viewing position. Maintaining a stable viewing position is also enhanced by the use of the window 20 as shown in FIG. 1.

A top view of the instrument is illustrated in FIG. 1a. Typical dimensions are given in FIG. 1a to illustrate the compacted size of the confocal imaging head 32. The elements in the head 32 may be located on a single board to provide unitized construction. The height of the head may be approximately two inches from the base to the nominal focal point of the focusing lens 18.

By scanning using the mechanical actuators 34 successive lines may be scanned at successive depths to provide images of vertical sections (i.e., along a vertical plane through the tissue sample). If desired the images may be formed from horizontal sections (i.e., along a horizontal plane through the tissue sample) as the lines are scanned horizontally. By tilting the sample, sections at desired angles to the surface of the sample (i.e., along a tilted or non-perpendicular plane) may be formed, such sections may also be formed by moving the lens 18 via actuator 34 as desired angles.

Referring to FIG. 2, there is shown a block diagram of the data acquisition and analysis system which is part of the imaging system 10 provided by the invention. The confocal head 32 is the head shown in FIGS. 1 and 1a. The output 36 from the head 32 is the output from the pinhole detector assembly 30. This output 36 is the confocal detector signal. Signals are also provided from sensors 38, namely a lateral position sensor and a vertical position sensor. These signals after amplification and filtering are acquired by a analog to digital converter of a digital I/O board 40. This board 40 may also be on a board with a circuit which provides a digital to analog channel to drive the lateral motion actuator. The vertical scanning actuator is driven from a signal derived from a conventional signal generator

42. The A to D, D to A and digital I/O board 40 is controlled and data is acquired via software in a personal computer 44, such as a Macintosh Quadra 950. Conventional software packages may be used for image analysis and for driving a display 46, which is shown by way of example as a 1472 by 1088 pixel display.

Referring to FIG. 3, there is shown the confocal imaging head 32 contacted against the skin 48 of a subject specimen using a mineral oil as an optical index matching fluid, which is an optical contact liquid 21 (FIG. 1) for reducing undesired reflections of light from the surface of the skin. The force against the skin 48 will be limited to that required to press the skin against the contact window 20 of the head 32. A laser beam 50 which may be relatively low power (e.g., 6.3 milliwatts of optical power) is focused into the dermis of the specimen. The laser is operated at a wavelength capable of penetrating into the skin of the specimen, thus the skin may be considered transparent to the laser wavelength (or in other words, the skin is permeable to electromagnetic radiation of specified frequencies). The depth of focal point or spot 52 is varied from the surface of the stratum corneum to a few millimeters below the surface of stratum corneum. The nominal beam spot size may be, for example, 2.5 micrometers, full width half maximum. The laser spot is scanned laterally across the skin, for example at a rate of 3 to 10 hz. Different laser wavelengths may be selectively used for different resolution. Inasmuch as the energy delivered is proportional to the illuminating flux focused divided by the diameter of the spot, the scan length and the scan rate or frequency, the amount of incident flux is sufficiently low that damage to the specimen is avoided. The light scattered by the tissue is collected and the lights coherent component is re-imaged onto the pinhole aperture 54 of assembly 30, as shown in FIGS. 1 and 1a. The pinhole 54 transmits the coherent light from the focal region of the incident beam 53 to the detector 55 (of assembly 30) where it converts the light into an electrical signal. As the lens 18

scans laterally, the electrical signal is acquired by the computer and stored. Each scan represents a one dimensional trace of the reflectivity and scattering cross section of the dermis at a given level below the surface of the skin 48. A series of scans are made with the focal point positioned at progressively lower depths thereby providing a vertical cross section image of the skin which may be similar to a B-scan ultrasound image. As stated earlier, these scans may also be horizontal to provide a horizontal cross-section, or at an angle to provide an angular cross-section of the skin.

From the foregoing description it will be apparent that there has been provided an embodiment of a confocal imaging system for dermatological pathology applications. Variations and modifications of the herein described system and other applications for the invention will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.

What is claimed is:

1. A confocal imaging system for dermatological examinations of a tissue sample which comprises:

a handheld housing;

confocal imaging optics in said housing for focusing and scanning a focal spot in a plane through the tissue sample; and

a source of laser illumination which illuminates the tissue sample through the confocal imaging optics.

2. The system of Claim 1 wherein said confocal imaging optics further comprises means for collecting and imaging reflected light from the illuminated tissue sample.

3. The system of Claim 1 wherein said source is enabled to provide laser illumination at a wavelength transparent to said tissue.

4. The system of Claim 1 wherein said confocal imaging optics comprises a lens, and means for moving the position of said lens to enable scanning of said focal spot through the tissue sample.

5. The system of Claim 4 wherein said moving means further comprises means for moving said lens in one of different said planes through the tissue sample so as to provide sections from the group consisting of: horizontally spaced sections, angularly spaced sections, and vertically spaced sections.

6. The system of Claim 4 wherein said moving means is provided by a plurality of positioning actuators.

7. The system of Claim 1 wherein said confocal imaging optics comprises means for converting said laser illumination into circularly polarized light to enable said

tissue sample to be illuminated by said circularly polarized light.

8. The system of Claim 7 wherein said confocal imaging optics further comprises means for collecting circularly polarized light reflected light from the illuminated tissue sample which is orthogonal to the circularly polarized light which illuminated the tissue sample.

9. The system of Claim 1 further comprising a window in said housing through which said confocal imaging optics illuminates said tissue sample, said window having a surface spaced from said tissue sample.

10. The system of Claim 9 further comprising an optical index matching fluid located between said surface of said window and said tissue sample.

11. The system of Claim 1 further comprising a detection system for receiving reflected light from the illuminated tissue sample, said received reflected light having a coherent component.

12. The system of Claim 11 wherein said detection system produces, responsive to said coherent component of said received reflected light, electrical signals representative of a section of said tissue sample.

13. The system of Claim 11 wherein said detection system further comprising a photo-detector assembly, and optical elements for relaying said coherent component of said reflected light to said photo-detector assembly, said photo-detector assembly being enabled to convert said coherent component of said reflected light into electrical signals.

14. The system of Claim 12 further comprising means for collecting data representative of said electrical signals, and means for processing said collected data to display a scan image of said tissue sample based on said collected data.

15. The system of Claim 11 wherein said confocal imaging optics, said detection system, and said source are a unitized construction in said housing.

16. The system of Claim 1 wherein said laser illumination from said source is a laser beam, said system further comprises a photo-detector assembly for converting received light into electrical signals, and said confocal imaging optics comprise:

a beam splitter for receiving said laser beam from said source at an oblique angle and providing a circular beam;

a plate incident to said circular beam which polarizes said circular beam to provide a circularly polarized beam;

a lens incident to said circularly polarized beam to focus said circularly polarized beam into said tissue sample and to collect light returned from said tissue sample;

said returned light being incident to said plate and then to said beam splitter; and

said beam splitter reflects part of said returned light incident thereto, and said reflected part of said returned light is optically coupled to said photo-detector assembly.

17. The system of Claim 16 wherein said returned light from said tissue collected by said lens has a component which is circularly polarized orthogonal to the beam focused into the tissue sample, said plate converts the component of the returned light into linearly polarized orthogonal light, and said beam splitter by reflecting part of said returned light filters said component from said returned light.

18. A method of providing a display of a section in dermal tissue (skin) below the surface of the skin which comprises the steps of:

directing a laser beam via confocal optics having a lens to the skin;

varying position of said lens to scan a focal spot over a succession of lines along a plane below the skin surface;

detecting and imaging light returned from the tissue as said spot scans;

converting said light into signals; and

processing said signals to provide a display of said section.

19. The method of Claim 18 wherein said laser beam operates at a wavelength transparent to the dermal tissue.

20. The method of Claim 18 wherein said step of detecting and imaging light is responsive to said position of said lens.

21. The method of Claim 18 said step of varying the position of said lens further comprises the step of varying the position of said lens to scan along said plane oriented below the skin surface so as to provide sections from the group consisting of: horizontally spaced sections, angularly spaced sections, and vertically spaced sections.

22. The method of Claim 18 wherein said step of directing a laser beam via confocal optics further comprises the steps of converting said laser beam into circularly polarized light, and illuminating said dermal tissue by said circularly polarized light.

23. The method of Claim 22 wherein said step of detecting and imaging light returned from the tissue further

comprises the step of collecting circularly polarized light reflected from the illuminated tissue sample which is orthogonal to the circularly polarized light which illuminated the tissue sample.

24. The method of Claim 18 wherein said step of directing a laser beam via confocal optics further comprises providing a window having a surface through which said confocal optics directs said laser beam to the skin, and providing an optical index matching fluid located between said surface of said window and said surface of said skin to reduce light reflected from the surface of the skin.

25. The method of Claim 18 wherein said step of directing a laser beam via confocal optics having a lens to the skin further comprises the steps of:

translating said laser beam into a circular beam;

circularly polarizing said circular beam; and

focusing with said lens said circularly polarized beam into said dermal tissue.

26. The method of Claim 25 wherein said step of detecting and imaging light returned from the tissue as said spot scans further comprises the steps of:

collecting with said lens light returned from said tissue sample, said returned light having a component of circularly polarized light orthogonal to said circularly polarized beam focused into said dermal tissue;

linearly polarizing said component of said returned light; and

filtering said linearly polarized component, wherein said converting step is responsive to said filtered linearly polarized component of said returned light.

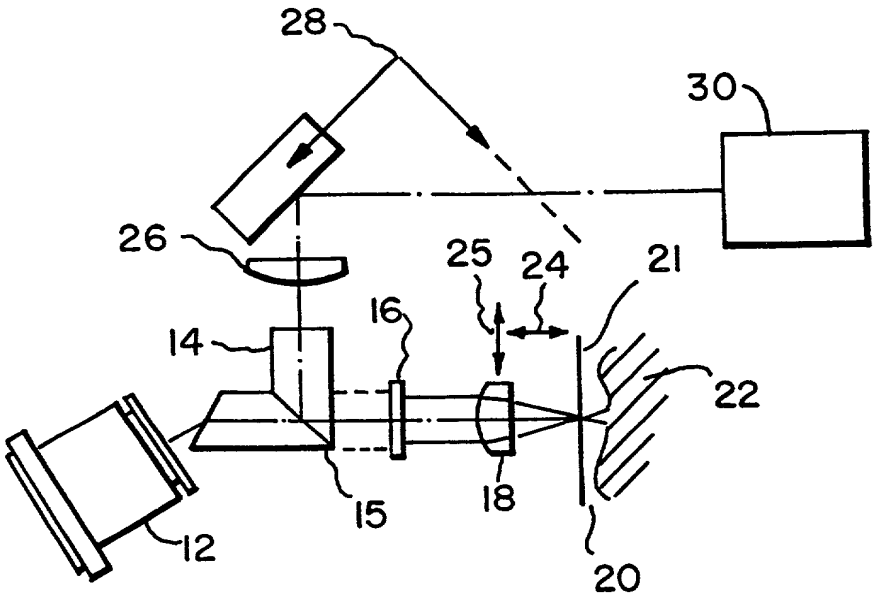

FIG. 1

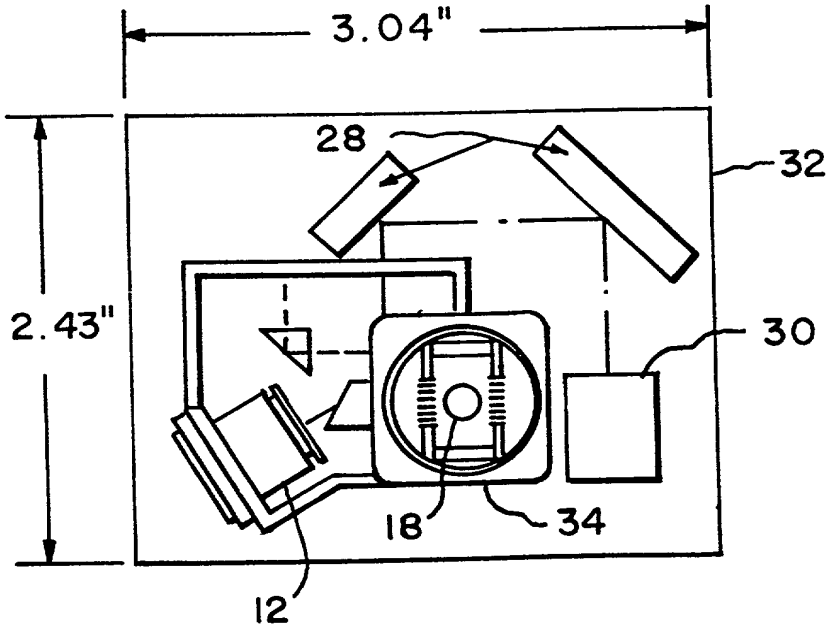

FIG. 1A

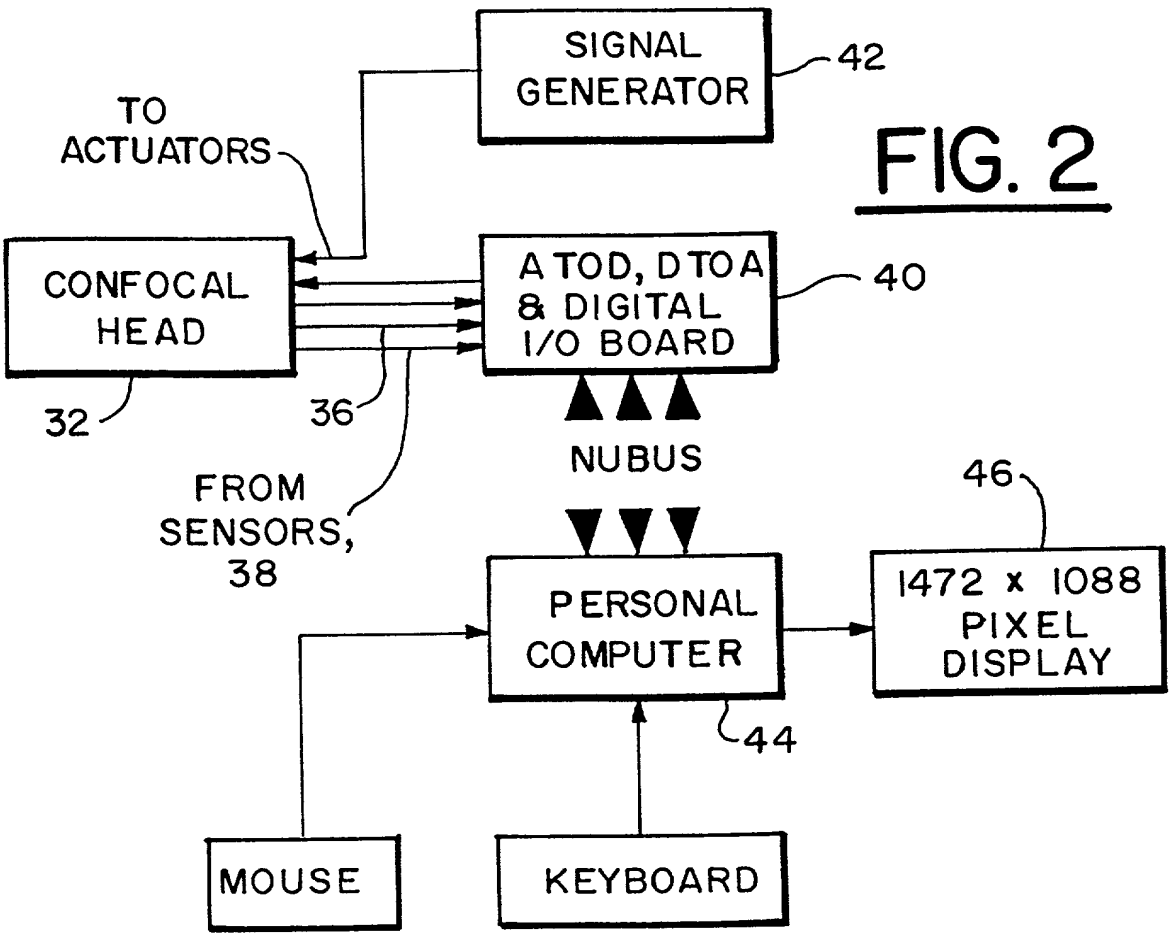
SIGNAL GENERATOR
42
TO ACTUATORS
CONFOCAL HEAD
A TOD, D TOA & DIGITAL I/O BOARD
40
32
36
FROM SENSORS, 38
NUBUS
46
PERSONAL COMPUTER
1472 x 1088 PIXEL DISPLAY
44
MOUSE
KEYBOARD

FIG. 2

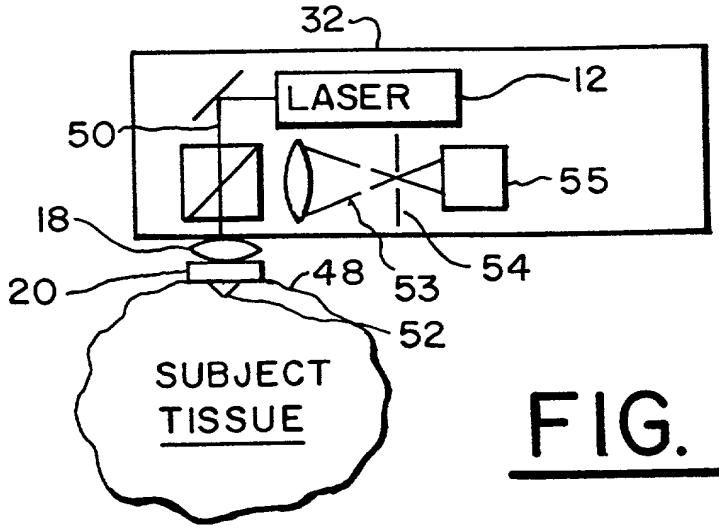
32
LASER
12
50
55
18
20
48
53
54
52
SUBJECT TISSUE

FIG. 3

DECLARATION AND POWER OF ATTORNEY

Docket No. ML-0362

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Confocal Imaging Through Thick Dermal Tissue the specification of which

(check one) X is attached hereto.

_____ was filed on _____ as Application Serial No. _____ and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specifications, including the claims, as amended by any amendment referred to above. To the best of my knowledge, information and belief the facts stated therein are true.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim priority benefits under Title 35, United States Code, §119 of any co-pending provisional application(s) or foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s) and Any Priority Claims under 35 U.S.C. §119:			Priority Claimed	
Provisional Appln. 60/001,141 (Number)	USA (Country)	07/13/95 (Day/Month/Year Filed)	X Yes	_____ No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	_____ Yes	_____ No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	_____ Yes	_____ No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

Serial No.	Filing Date	(Status: patented, pending, abandoned)
_____	_____	_____
Serial No.	Filing Date	(Status: patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint MARTIN LUKACHER, Registration No., 17,788 and Kenneth J. LuKacher, Registration No. 38,539 with full power of substitution, association and revocation, as attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. Send all correspondence to Suite 1000, Clinton Square, Rochester, New York 14604-1792.

Please direct all telephone calls to the first named attorney at telephone No. (716) 263-1253 and send all correspondence to the above address.

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Same

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Full name of fourth inventor

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Citizenship

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Post Office Address

Same

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Change Of Attorney Or Agent's Address In Application (37 CFR 1.8(a))	Docket No. ML-0362C2

In Re Application Of: **James M. Zavisland and Jay M. Eastman**

Serial No.	Filing Date	Examiner	Group Art Unit
Cont. of 09/001,016	**Concurrently herewith**	**N/A**	**N/A**

Invention: **CONFOCAL IMAGING THROUGH THICK DERMAL TISSUE**

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Registration Number & Address of Attorney or Agent of Record

I certify that this document is being deposited on with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence